Sandia National Laboratories

Quality Work Plan

Probabilistic Assessment of Waste Qualification

Effective Date: 7/~~3~~17/2001

Preparer:	*Original Signed By F.J. Schelling*	Date:	7/~~2~~16/2001
Reviewer:	*Original Signed By L.C. Sanchez*	Date:	7/~~2~~16/2001
QA Review:	*Original Signed By R.R. Richards*	Date:	7/~~2~~16/2001
Approved:	*Original Signed By P.I. Pohl*	Date:	7/~~3~~16/2001

1.0 Revision History

The Quality Work Plan is a controlled document. Changes to the Quality Work Plan will be reviewed in accordance with document review controls in Appendix B and approved by the Project Lead as shown on the cover page of this document. Changes that are clearly editorial in nature do not require review and approval, but will be issued as a revision. Following approval, the controlled, online version of the Quality Work Plan will be established and maintained by the Quality Assurance (QA) Lead. The need to perform expedited changes to the Quality Work Plan is not anticipated and will follow the same process as a typical revision.

Revision	Description	Effective Date
0	Initial issue	6/18/2001
1	Clarifications and additional requirements added per Supplier Qualification Audit	7/3/2001
2	Modification to add clarification and implementation to resolve remaining concerns from Supplier Qualification Audit	7/17/2001

2.0 Work Scope and Objectives

This work scope consists of two tasks: Task A – Decision Analysis for Waste Qualification; and Task B – Independent Assessment and Verification. The work scopes for the two individual tasks are described in more detail below. Products of this work are intended to serve a programmatic purpose in support of strategic management decisions associated with establishing process and sampling methods and controls.

2.1 Task A – Potential for Optimizing HLW Sampling

A systematic decision analysis will be performed and documented that synthesizes existing data and related uncertainties and variations. Impacts of uncertainty and variations in the feed, processing, sampling, and analytical systems will be assessed. The analysis will be a Multi-Attribute Utility Analysis. Distinct attributes and constraints to be considered include cost, turnaround, radiological risk for workers and the public, schedule, quality, etc. Data and related uncertainties and variations for each alternative will be compiled relying upon existing information where available and subjective judgment of relevant staff where not available. The task includes:

- Define attributes
- Model any necessary processes for the evaluation of alternatives defined by options 1 (sample and analyze immobilized high level waste {IHLW} product), 2 (sample and analyze melter feed slurry), and 3 (sample and analyze high level waste (HLW) from the concentrate receipt vessel, calculate glass former chemicals (GFC) additions and the resulting product compositions).
- Quantify appropriate uncertainties
- Elicit and construct single-attribute utility functions
- Calculate single attribute utilities

- Combine for use with an appropriate Multi-Attribute Utility Analysis
- Verify assumptions
- Compute expected utilities for each alternative
- Perform sensitivity and importance analysis
- Develop relationship diagrams associating the results of the sensitivity analyses with the cost and schedule of reducing uncertainty providing a distinct relationship of cost, schedule, and risk.
- Prepare reviewed reports to document the work performed.

2.2 Task B – Impact of Variances and Uncertainties in HLW Process Controls on Product Quality

The draft report titled, "HLW Process Control Verification, Product Quality Variance and Uncertainties" is due for review during last week of May 2001. The following parameters should be considered to perform independent assessment and verification using a probabilistic assessment tool incorporating total system attributes.

- Quantify the sources of variation and uncertainty affecting estimates of glass composition. This includes variation in glass composition for the selected waste type, sampling uncertainty, and analytical uncertainty.
- Evaluate the non-radioactive property-composition database used to develop property-composition models and corresponding uncertainty expressions.
- Perform sensitivity analysis to characterize uncertainty realistically based on available information (i.e. re-evaluate existing sampling and process strategies to ensure uncertainty is treated consistently throughout the whole system)
- Perform a probabilistic assessment to determine the probability of the selected waste stream to fail the disposal waste acceptance criteria (WAC).
- Prepare reviewed reports to document the work performed.

3.0 Deliverables and Schedule

Task A	**Duration**
Prepare draft report	7 weeks from award
Internal review	4 weeks
Final Report-Review/comments resolution	5 weeks

Task B	
Review draft report	9 weeks
Final Report with comments resolution	5 weeks

NOTE: Bechtel submittal to DOE - **14 SEP 01**

4.0 QA Controls

4.1 QA Policy Statement

The Project Lead has overall responsibility for achieving and maintaining quality as defined in this Quality Work Plan. All work within the scope of this plan is to be conducted by qualified staff in accordance with the controls specified in the Quality

Work Plan. These individuals have the responsibility for achieving and maintaining quality in the performance of their work. If work cannot be accomplished as described by these controls or would result in an undesirable situation, work shall be stopped and not resumed until the Quality Work Plan is changed to reflect current work practices. Quality achievement shall be verified independently by Sandia National Laboratories (SNL) and/or Bechtel National, Inc. (BNI) QA.

Applicable quality assurance requirements from the Office of Civilian Radioactive Waste Management's Quality Assurance Requirements and Description document (QARD, DOE/RW-0333P Revision 10) are identified in the QARD Requirements Matrix shown in Appendix A.

Controls on the conduct and documentation of analysis, software control, document review, and records processing are provided in Appendix B.

Internal audits shall be performed by qualified auditors in accordance with QARD Section 18.0 to verify compliance with, and to determine effectiveness of, the Quality Work Plan.

The following table shows the relationship between the applicable sections of the QARD and 10 CFR 830.120, "Quality Assurance Program Requirements." Shaded columns indicate QARD criteria that are not applicable to this work. As shown in the table, the Quality Work Plan addresses all but Criteria 6, 7, and 8 of 10 CFR 830.120, which are not applicable to this scope of work.

QARD →	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	S1	S2	S3	S4	S5	A	B	C
10CFR830.122																										
Management Criteria																										
Criterion 1-Program.	X																									
Criterion 2-Personnel Training and Qualification.		X																								
Criterion 3-Quality Improvement		X													X											
Criterion 4-Documents and Records.					X	X											X									
Performance Criteria																										
Criterion 5- Work Processes.					X			X				X	X													
Criterion 6-Design.			X																							
Criterion 7-Procurement.				X			X																			
Criterion 8-Inspection and Acceptance Testing.							X			X	X															
Assessment Criteria																										
Criterion 9-Management Assessment.		X																								
Criterion 10-Independent Assessment.																		X								

4.2 Identification and Resolution of Conditions Adverse to Quality

A condition adverse to quality shall be identified when a requirement of the Quality Work Plan or the QARD is not met. Such conditions shall be documented and reported to the Project and QA Leads.

The QA Lead shall determine if a condition adverse to quality is significant, and if so, if a stop work condition is warranted. The QA Lead notifies the Project Lead when a stop work condition exists, and removes the stop work based on the resolution of the related condition. A significant condition adverse to quality is one, which if uncorrected, could have a serious effect on radiological safety of the public.

For all conditions adverse to quality, including significant conditions, the Project Lead ensures that technical personnel perform an investigation to determine the extent and impact of the condition, take appropriate remedial action, determine the root cause, and take action to prevent recurrence.

The QA Lead shall notify the BNI technical representative and shall concur with proposed corrective action to ensure that QA program requirements are satisfied. The QA Lead shall verify implementation of corrective actions and close the corrective action documentation in a timely manner when actions are complete.

Differences of opinion regarding QA program requirements shall be brought to the attention of the Project Lead, and if not resolved, elevated progressively to SNL and BNI management.

4.3 Personnel Qualification and Training

Position descriptions and minimum education and experience requirements for personnel assigned to conduct or verify technical analyses, and independent auditors of the work, will be defined by the responsible SNL line manager and documented in ~~a~~ the QA record. In addition, auditors conducting internal QA audits shall be qualified and conduct the audit in accordance with QARD Section 18.0. Personnel who do not meet these minimums but have sufficient experience may be assigned to this work with the documented justification and approval of project management. The assigned Project Lead, whose qualifications are verified by SNL management, has responsibility for confirming the qualifications of SNL personnel assigned to conduct or verify technical analysis by contacting SNL Human Resources to verify that each individual satisfies the education and experience requirements.

Training for this work requires individuals to read and understand the Quality Work Plan. Documentation of the verification of qualifications and completion of training will be included in the QA records of this work.

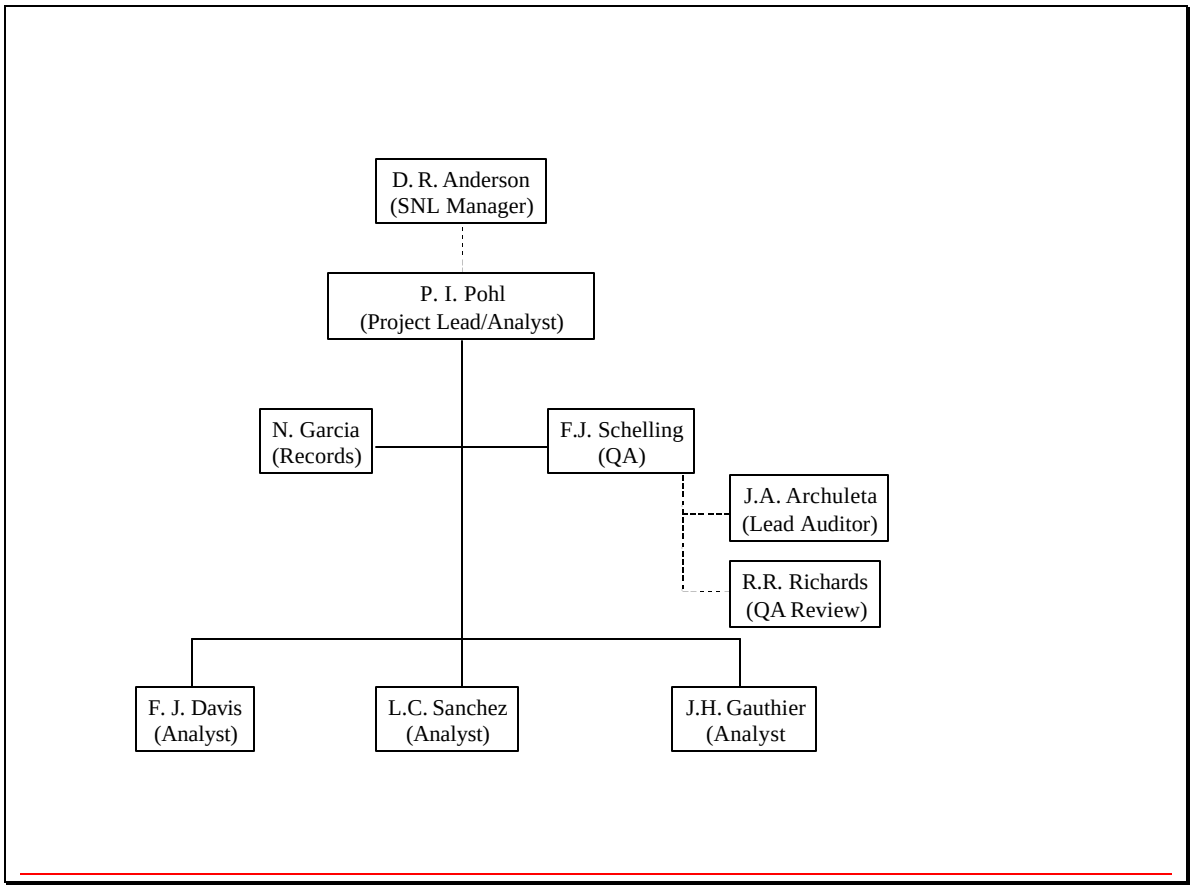
Personnel qualifications and training must be completed and documented prior to the initiation of work on this project.

5.0 Organization and Interfaces

Work requirements are specified in the BNI procurement document. SNL work will be performed by a small team of qualified personnel under an assigned Project Lead. No formal interfaces, other than that established by BNI procurement document, are necessary. Position assignments for this work are shown in the following table, and an organizational structure is shown in the figure.

Name	Position
D. R. Anderson	Line Manager
P. I. Pohl	Project Lead/Analyst

F. J. Davis	Analyst
L. C. Sanchez	Analyst
J. H. Gauthier	Analyst
F. J. Schelling	QA Lead
R. R. Richards	Independent QA Support
N. Garcia	Records Support
J. A. Archuleta	Lead Auditor



6.0 Acceptance Criteria

Objective evidence to demonstrate that the work was performed as required will be acceptance of the final deliverable reports and associated QA records.

7.0 Records

QA records generated by this work will be maintained in temporary storage either in dual storage or a one-hour fire rated container at SNL until transmitted to BNI. A copy will be retained at SNL until receipt is acknowledged by BNI. QA records include:

- Quality Work Plan and revisions
- Qualification and training records

- Analysis records
- Review documentation
- Software records
- Final deliverable reports

8.0 Appendices

Appendix A. QARD Requirements Matrix

Appendix B. Supplemental Quality Assurance Controls

QARD Section	QARD Section Title	Applicability	Implementation Comment
1.0	**ORGANIZATION**	N/A*	Descriptive
1.1	GENERAL	N/A	Descriptive
1.2	REQUIREMENTS	Applies	Organization and responsibilities incorporated into Quality Work Plan, Section 5.0 (Note: exception taken to OQA acceptance requirement.)
1.2.1	Line Management	Applies	Quality Work Plan, Section, 5.0
1.2.2	Quality Assurance Management	Applies	Quality Work Plan, Section 4.1. Delegation of responsibility to SNL assumed (with oversight by BNI QA). Note that per 1.2.2.A, SNL QA and work performed by staff, not management.
1.2.3	Responsibility for Quality	Applies	Quality Work Plan, Section 4.1, assigns responsibilities, including independent verification.
1.2.4	Delegation of Work	N/A	No delegation of work anticipated.
1.2.5	Resolution of Quality Disputes	Applies	Quality Work Plan, Section 4.2. Resolution of such issues to involve SNL and BNI management.
1.3	DESCRIPTION	N/A	Descriptive
1.3.1	General Description of the OCRWM	N/A	OCRWM organization description is not relevant to this work.
1.3.2	Specific Civilian Radioactive Waste Management Offices	N/A	OCRWM organization description is not relevant to this work.
1.3.3	Other OCRWM Affected Organizations	Applies	Per 1.3.3A, Quality Work Plan serves as controlled implementing document to establish controls on work. Applicable QARD requirements are specified in BNI-SNL procurement documents. Overview provided by BNI QA, not OCRWM. Note 1.3.3B is not applicable as this work is not in direct support to OCRWM.
Fig. 1-1	Office of Civilian Radioactive Waste Management	N/A	Descriptive
2.0	**QUALITY ASSURANCE PROGRAM**	N/A	Descriptive
2.1	GENERAL	N/A	Descriptive
2.2	REQUIREMENTS	N/A	Descriptive
2.2.1	QA Program Documents	Applies	2.2.1A – policy stated in approved Quality Work Plan, Section 4.1. 2.2.1B1 – exception taken to “structured series” as implementation is specified in Quality Work Plan 2.2.1C – This matrix (Quality Work Plan, Appendix A) satisfies the requirement and will be included in the Quality Work Plan; exception taken to 2.2.1C2 and 2.2.1C4 re OQA review; BNI will review.
2.2.2	Classifying Items	N/A	This work does not involve designed items.

QARD Section	QARD Section Title	Applicability	Implementation Comment
2.2.3	Controlling Activities	Applies	QA program applies per 2.2.3D.
2.2.4	Applying QA Controls	Applies	Appropriately graded controls are established in the Quality Work Plan (primarily per 2.2.4A-D).
2.2.5	Planning Work	Applies	Quality Work Plan
2.2.6	Surveillances	Applies	If surveillances are performed, this is BNI responsibility.
2.2.7	Management Assessments	N/A	Not considered relevant for this workscope.
2.2.8	Readiness Reviews	N/A	Not considered relevant for this workscope.
2.2.9	Peer Reviews	N/A	Not considered relevant for this workscope.
2.2.10	Document Review	Applies	Quality Work Plan and product documents are reviewed per these requirements (Quality Work Plan, Appendix B, Section B.3..
2.2.11	QA Program Information Management	Applies	QA program status will be supplied to BNI as appropriate.
2.2.12	Personnel Qualification	Applies	Quality Work Plan, Section 4.3, identifies personnel, minimum qualifications, and any relevant training. (Per 2.2.12.B1, all personnel are assigned as technical analysts.)
2.2.13	Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing, and Auditing	Applies	Quality Work Plan Sec.4.1 requires internal audits performed by qualified auditors.
5.0	**IMPLEMENTING DOCUMENTS**	N/A	Descriptive
5.1	GENERAL	N/A	Descriptive
5.2	REQUIREMENTS	Applies	Quality Work Plan will be a controlled document.
5.2.1	Types of Implementing Documents	Applies	The Quality Work Plan will specify all controls applicable to the work.
5.2.2	Content of Implementing Documents	Applies	The Quality Work Plan includes the appropriate information required by this section.
5.2.3	Review and Approval of Implementing Documents	Applies	Document Review – Quality Work Plan, Appendix B
5.2.4	Compliance with Implementing Documents	Applies	Addressed in the Quality Policy Statement of the Quality Work Plan.
6.0	**DOCUMENT CONTROL**	N/A	Descriptive
6.1	GENERAL	N/A	Descriptive
6.2	REQUIREMENTS	N/A	Descriptive
6.2.1	Types of Documents	Applies	Quality Work Plan will be a controlled document.

QARD Section	QARD Section Title	Applicability	Implementation Comment
6.2.2	Preparing Documents	Applies	Quality Work Plan identifies preparation and maintenance responsibilities by preparer on cover page.
6.2.3	Reviewing Documents	Applies	Document Review – Quality Work Plan, Appendix B
6.2.4	Approving Documents	Applies	Quality Work Plan identifies approval authority on cover page.
6.2.5	Distribution and Use of Documents	Applies	Quality Work Plan will be a controlled document (Quality Work Plan, Section 1.0).
6.2.6	Changes to Documents	Applies	Quality Work Plan, Section 1.0 includes description of change process.
6.2.7	Expedited Changes	Applies	Unlikely to be necessary, but is described in Section 1.0 of Quality Work Plan.
6.2.8	Editorial Corrections	Applies	Quality Work Plan, Section.1.0.
16.0	**CORRECTIVE ACTION**	N/A	Descriptive
16.1	GENERAL	N/A	Descriptive
16.2	REQUIREMENTS	N/A	Descriptive
16.2.1	Identifying Conditions Adverse to Quality	Applies	Quality Work Plan, Section 4.2.
16.2.2	Classification of Conditions Adverse to Quality	Applies	QA Lead will determine if identified deficiencies are significant (QWP, Section 4.2).
16.2.3	Conditions Adverse to Quality	Applies	QA Lead concurs with remedial action and notifies BNI (QWP, Section 4.2).
16.2.4	Significant Conditions Adverse to Quality	Applies	QA Lead will determine if identified deficiencies are significant or require a stop work. (QWP, Section 4.2).
16.2.5	Follow-up and Closure Action	Applies	SNL will notify BNI of completion of corrective action and of independent verification. (QWP, Section 4.2).
16.2.6	Quality Trending	N/A	Not considered relevant for this workscope.
17.0	**QUALITY ASSURANCE RECORDS**	N/A	Descriptive
17.1	GENERAL	N/A	Descriptive
17.2	REQUIREMENTS	N/A	Descriptive
17.2.1	Classifying Quality Assurance Records	Applies	Criteria 17.2.1A2, 5, and particularly 7 and 8 are used to identify lifetime QA records; others will be identified as nonpermanent per 17.2.1.B. Responsibility for storage and preservation of QA records transfers to BNI upon transmittal and receipt.
17.2.2	Creating Valid Quality Assurance Records	Applies	Quality Work Plan, Section 7.0 identifies documents that will become QA records. See also QWP Appendix B.4.
17.2.3	Receiving and Indexing Quality Assurance Records	Applies	SNL will compile and manage QA records until transmitted to BNI per Quality Work Plan, Section 7.0.; QWP Appendix B.4 establishes indexing until accepted by BNI.
17.2.4	Correcting Information in Quality Assurance Records	Applies	Quality Work Plan, Appendix B, Records Processing

QARD Section	QARD Section Title	Applicability	Implementation Comment
17.2.5	Storing and Preserving Quality Assurance Records	Applies	SNL will provide interim storage until transmittal to BNI.
17.2.6	Retrieval of Quality Assurance Records	N/A	Not considered relevant for this workscope.
17.2.7	Retention of Quality Assurance Records	N/A	Exception taken to 17.2.7, which is BNI's responsibility.
17.2.8	Turnover of Quality Assurance Records	Applies	SNL submits QA records to BNI. Exception taken to 17.2.8B and 17.2.8C as not appropriate.
17.2.9	Long Term Single Storage Facility	N/A	OCRWM responsibility.
17.2.10	Dual Storage Facilities	N/A	OCRWM responsibility.
17.2.11	Temporary Storage Facility	Applies	SNL will provide appropriate temporary storage facilities as needed (QWP Sec.7.0.).
17.2.12	Replacement of Quality Assurance Records	Applies	Process described in Section. 7.0 of Quality Work Plan
18.0	**AUDITS**	N/A	Descriptive
18.1	GENERAL	N/A	Descriptive
18.2	REQUIREMENTS	N/A	Descriptive
18.2.1	Scheduling Internal Audits	Applies	SNL plans to perform one internal audit during the work.
18.2.2	Scheduling External Audits	N/A	No external auditing.
18.2.3	Audit Schedule	N/A	Short term work; no need for annual schedules.
18.2.4	Audit Planning	Applies	Audits will be performed by ~~NQA~~ qualified auditors, who will be provided Sec.18.0 requirements for planning and conducting audits.
18.2.5	Audit Team Independence	Applies	Qualified auditors will be independent from the work.
18.2.6	Audit Team Selection	Applies	Auditor responsibility
18.2.7	Performing Audits	Applies	Auditor responsibility
18.2.8	Reporting Audit Results	Applies	Auditor responsibility
18.2.9	Responding to Audits	Applies	SNL will provide responses to audit findings.
18.2.10	Evaluating Audit Responses	Applies	Coordinated with auditor
18.2.11	Follow-up Action	Applies	Coordinated with auditor
18.2.12	Technical Specialist Qualifications	N/A	Not anticipated due to limited work scope.
18.2.13	Auditor Qualifications	Applies	SNL will obtain verification of auditor qualifications for internal audits.
18.2.14	Lead Auditor Qualifications	Applies	See 18.2.13
18.2.15	Lead Auditor Education and Experience	Applies	See 18.2.13

QARD Section	QARD Section Title	Applicability	Implementation Comment
18.2.16	Lead Auditor Communication Skills	Applies	See 18.2.13
18.2.17	Lead Auditor Training	Applies	See 18.2.13
18.2.18	Lead Auditor Audit Participation	Applies	See 18.2.13
18.2.19	Lead Auditor Examination	Applies	See 18.2.13
18.2.20	Certification of Lead Auditor Qualifications	Applies	See 18.2.13
18.2.21	Maintaining Lead Auditor Proficiency	Applies	See 18.2.13
SUPPLEMENT I	**SOFTWARE**	N/A	Descriptive
I.1	GENERAL	Applies	Note that anticipated software use is of the nature of software routines and macros using commercial software subject only to Supplement I.2.1C. BNI has responsibility for software used to provide output to SNL.
I.2	REQUIREMENTS	N/A	Descriptive
I.2.1	General Software Requirements	Applies	Software applications will be documented per I.2.1C. Exception to I.2.1A and B - SNL will not develop or modify software.
I.2.2	Software Planning	N/A	Per QARD, Supp. I, 1.1, paragraph I.2.1C applies.
I.2.3	Software Life Cycle Requirements	N/A	Per QARD, Supp. I, 1.1, paragraph I.2.1C applies.
I.2.4	Software Configuration Management	N/A	Per QARD, Supp. I, 1.1, paragraph I.2.1C applies to most software for this work. Configuration controls for LHS are established in QWP Section B.2.2.
I.2.5	Defect Reporting and Resolution	N/A	Per QARD, Supp. I, 1.1, paragraph I.2.1C applies.
I.2.6	Software Procurement	N/A	Not applicable to this work scope.
I.2.7	Software Previously Developed Not Using This Supplement	N/A	Application limited to a controlled version of the LHS code per QWP Section B.2.2
I.2.8	Control of the Use of Software	N/A	Similar controls established under I.2.1C.
SUPPLEMENT III	**SCIENTIFIC INVESTIGATION**	N/A	Descriptive
III.1	GENERAL	Applies	Requirement to control software per Supplement I.
III.2	REQUIREMENTS	N/A	Descriptive
III.2.1	Planning Scientific Investigations	Applies	The Quality Work Plan serves as the planning document.

QARD Section	QARD Section Title	Applicability	Implementation Comment
III.2.2	Performing Scientific Investigations	Applies	Per III.2.2A, the Quality Work Plan will be the implementing document to control this work; III.2.2B and C are not applicable. See Quality Work Plan Sec.4.1..
III.2.3	Data Identification	Applies	Quality Work Plan, Appendix B.1.2, bullet 4. Sources of any data used will be identified in a traceable manner.
III.2.4	Data Review, Adequacy, and Usage	Applies	III.2.4A applies and is implemented in the Quality Work Plan, Appendix B, Conducting and Documenting Analysis. Exceptions taken to III.2.4B and C, as the results of this work are not intended to be directly relied upon for safety and waste isolation issues.
III.2.5	Technical Report Review	Applies	Quality Work Plan, Appendix B, Document Review
III.2.6	Model Development and Use	N/A	Model development is not included in the work scope.
SUPPLEMENT V	**CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA**	N/A	Descriptive
V.1	GENERAL	N/A	Descriptive. References Supplement I and III controls.
V.2	REQUIREMENTS	N/A	Descriptive
V.2.1	Control of the Electronic Management of Data	N/A	Per V.1, applicable Supplement I and III controls apply. Additional controls on data transfer and data protection are defined in QWP, Sec.B.2.3.
APPENDIX A	**HIGH-LEVEL WASTE FORM PRODUCTION**	N/A	Descriptive
A.1	GENERAL	N/A	A.1A is descriptive; A.1B applies only to DOE/EM.
A.2	REQUIREMENTS	N/A	Descriptive
A.2.1	Amplification of QARD Section 2.0, Quality Assurance Program	N/A	Not applicable to the workscope.
A.2.2	Amplification of QARD Supplement III, Scientific Investigation	N/A	Not applicable to the workscope.

* N/A: Not Applicable

B.1 Conducting and Documenting Analysis

Analyses shall be documented to permit an independent qualified individual to confirm the analysis results or to repeat the analysis and achieve comparable results. All data used in the analysis shall be identified by reference to its source and qualification status. Analysis documentation is a non-permanent quality assurance record. Upon completion, individual records will be dated and signed by the records source and maintained in temporary storage by the Records Management System. Upon completion of the workscope, the records will be combined into a records package and transmitted to Bechtel.

1 The analyst documents the analysis or calculation in sufficient detail to establish the reproducibility of the analysis and analysis results by an independent, qualified reviewer.

2 Analysis documentation prepared by the analyst includes the following minimum content:

- Definition of the objective of the analysis
- Identification of the analysis date, analyst, and technical reviewer
- A description of the methods used to perform the analysis
- Identification of input data and their sources adequate to establish traceability to associated documentation and data qualification status
- Assumptions and their justification
- Identification of software used and independent software routine verification results, including documentation of any macro coding used for the analysis.
- A description of any checks made of the calculation.

3 The analyst submits the analysis documentation for technical review and documents the results in accordance with the document review process. Review criteria include establishing that the analysis is described in sufficient detail to trace the analysis and confirm the results or to permit independent repetition to achieve comparable results. Additional technical review criteria include consideration of the applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. If software is used in the analysis, the review establishes that the software is suitable to the problem being solved.

4 Upon completion of the analysis, the analyst checks to ensure that the documentation is complete and submits it for temporary storage to the Records Management System.

B.2 Software Use and Control

B.2.1 Routines and Macros

Software used for this work other than the Latin Hypercube Sampling (LHS) code (See B.2.2) must meet the QARD definition of a software routine, i.e. "Software routine: A collection of computer macros or script files, a spreadsheet application, or other stand-alone software application (either acquired or developed) that generally operates within another program, such as a spreadsheet, and must be independently verified by visual inspection and/or hand calculation."

Prepare documentation following Steps 1-4c below and provide it for independent verification (per Step 4d) to a qualified individual other than the originator. Following verification, the reviewer documents the results and returns the information to the originator.

1. Describe the purpose of the routine, how it was developed and verified.
2. Identify the software routine by a unique name and version number.
3. Identify the program used to develop the routine by name and version number.
4. Provide documentation to verify that the routine works as intended, including:
    a. A listing of input data,
    b. Results generated by the routine over a range of input parameters,
    c. Documentation of the routine programming (e.g., program listings, spreadsheet cell macros), and
    d. Documentation that the routine was independently verified by inspection and/or hand calculation.

The originator is responsible for ensuring that documentation of this process is included with the records of products in which the routine is used.

B.2.2. Use of Existing Developed Software (limited to LHS)

LHS software is subject to the following controls established to satisfy QARD I.2.7 requirements:

- The software user shall establish configuration controls for the LHS code prior to use, including defining the controlled software by a unique identifier, including version or revision, and associating the unique identifier with the associated documentation. Change control and status accounting are not applicable because no changes to the baselined, controlled code are anticipated or allowed.
- The software user shall perform, document, and subject to independent review an evaluation of the LHS code and its documentation to determine its adequacy for use for the work, the adequacy of user information (per QARD I.2.3.C.3), and the availability and results of software tests performed to validate the acceptability of the software for the subject application.

- Upon completion of the validation testing and documentation review, the controlled version of LHS may be used for the analysis.

B.2.3 Electronic Data Controls

- Transfers of electronic data between systems, and in particular between SNL and BNI, shall be checked by the user to verify proper transfer.
- Appropriate standard controls, such as backups, dual storage, and password protections, shall be established by the user to ensure that electronic data are properly identified, protected against damage or loss, and that data security and integrity are maintained

B.3 Document Review

Documents shall be reviewed for applicability, correctness, technical adequacy, completeness, accuracy, and compliance with requirements.

Reviewers shall be independent from the work being reviewed, technically competent for the subject under review, and provided access to pertinent background information if needed. The review requester shall ensure that the reviewer's qualifications have been documented and verified.

Mandatory comments shall be documented and resolved before the document is approved for release.

B.4 Records Processing

Individuals creating records shall ensure that QA records are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the activity, and shall protect them until submitted for temporary storage to the Records Management System and ultimate transfer to BNI. Individuals submitting records to temporary storage shall include an indexed listing of submitted records, including identification of the record source, title, page count, and record date. Corrections to records shall be made by drawing a single line through the deletion, including the initials or signature of the person authorized to make the correction, the date the correction was made, and the corrected information provided in proximity to or referenced by the correction.